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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61M 16/00, 16/20, 16/12

A1

(11) International Publication Number: **WO 99/13931**

(43) International Publication Date: 25 March 1999 (25.03.99)

(21) International Application Number: PCT/IE98/00079

(22) International Filing Date: 18 September 1998 (18.09.98)

(30) Priority Data:
60/059,264 18 September 1997 (18.09.97) US

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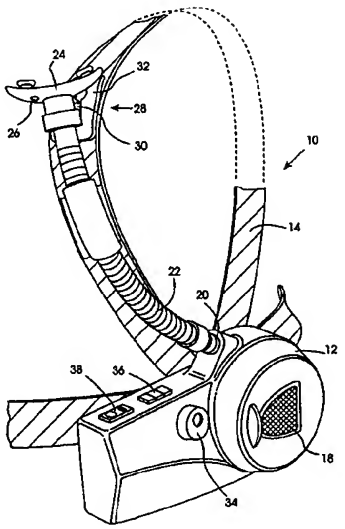
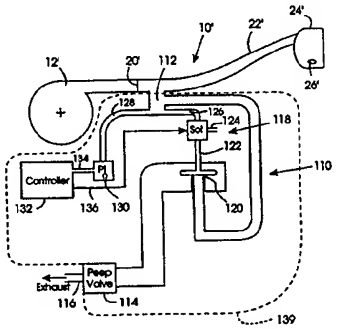
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PORTABLE RESPIRATOR





(57) Abstract

Apparatus (10) for treating dyspnea and improving exercise tolerance in an ambulatory patient comprising: a housing (12) defining a form factor having an air inlet (18) and an air outlet (20), the housing (12) being sufficiently small to be readily mounted to the body of an ambulatory patient (39); a pressure generator (41) within the defined form factor of the housing (12) for drawing ambient air into the air inlet (18) and delivering the air at a select pressure greater than ambient pressure to the outlet (20); a strap (14) on the housing (12) for releasably attaching the housing (12) to the patient (39); a flexible conduit (22) attached at a proximal end to the air outlet (20) of the housing (12); a connector (24) attached at a distal end of the conduit (22) for connecting the distal end of the conduit (22) to an airway of the patient (39); and a releasable coupling (28) between the strap (14) and the connector (24).

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PORTABLE RESPIRATOR

BACKGROUND OF THE INVENTION

Technical Field

The present invention is directed toward relieving dyspnea and improving exercise tolerance in patients subject to respiratory distress, and more particularly toward a method and apparatus for relieving dyspnea and improving exercise tolerance in ambulatory patients subject to respiratory distress.

Background Art

Patients subject to respiratory disorders such as Chronic Obstructive Pulmonary Disease ("COPD") often suffer dyspnea or breathlessness while exercising. By "exercising" we mean activities beyond the resting state, e.g., the act of walking short distances. The dyspnea and the fear of a spell of dyspnea creates great anxiety in such patients and can severely limit their ability to perform even the most simple tasks such as walking to the end of the driveway to pick up a newspaper. There is, therefore, a compelling need for a way of preventing or relieving a spell of dyspnea and improving exercise tolerance in such ambulatory patients. Such relief will allow greater mobility for such patients so that they can perform more functions on their own, thereby enhancing the patient's quality of life while reducing dependence on costly outside assistance.

One method of treating dyspnea is application of medication such as bronchodilators. While in some instances such medications can be effective for a given patient, they do not provide immediate relief from the dyspnea and sometimes do little to improve exercise tolerance. Thus, a patient who is out for a walk may be forced to endure the dyspnea for a considerable period of time before experiencing any relief. The resultant anxiety such a patient suffers while being extremely short of breath can exasperate the dyspnea causing the patient to become disoriented and unstable, subjecting

the patient to potential serious injury. Moreover, a given bronchodilator may not be effective for a given patient.

Another method for treating dyspnea and improving exercise tolerance is providing supplementary oxygen from either a gaseous or liquid oxygen supply. This method attempts to relieve the patient by enriching the oxygen content of the limited amount of air the patient is able to breathe while subject to COPD. Unfortunately, merely providing oxygen enriched air does not relieve the distressful feeling of the patient in many instances, for example where dynamic hyperinflation of the lungs exists. Therefore, supplementary oxygen in such instances does little to treat or prevent dyspnea, but merely tries to ensure the patent will get a sufficient supply of oxygen in their blood stream. These oxygen supplementing devices also suffer other serious problems. Gas delivery devices are inherently bulky and heavy by virtue of the compressed gas having to be contained in a sufficiently thick walled cylinder. Liquid delivery systems do not afford the patient the capability of refilling the liquid oxygen without access to a liquid base station. Moreover, both systems require constant replenishment, making the systems both inconvenient and expensive.

Continuous Positive Airway Pressure ("CPAP") devices are well known in the art and have been used to provide respiratory assistance and to treat breathing disorders such as COPD and Obstructive Sleep Apnea ("OSA"). One example of a device capable of providing CPAP which may be beneficial for treating dyspnea for a non-ambulatory patient is described in Rapoport, U.S. Patent No. Re. 35,339. However, such a device is unsuited for treatment of an ambulatory patient because it is bulky and heavy to carry and does not allow control of pressure by the patient.

CPAP is also a ventilation mode available on commercial intensive care unit ventilators and is typically used to wean a patient off a ventilator post-operatively. Portable ventilators such as the AUTOVENT 2000 and 3000 are available for emergency life support, but require a source of pressurized air from a gaseous supply, and therefore suffer the problems discussed above. The LP6 volume ventilator distributed by Aequetron can provide alternative ventilation modes, but cannot provide CPAP. In

addition, it is too heavy and bulky for attachment to an ambulatory patient, and is in fact typically used for wheel chair bound patients.

The prior art also teaches a variety of portable personal ventilating systems for delivering filtered air to a user in a contaminated environment. For example, O'Connor, U.S. Patent No. 4,590,951, teaches a body mounted blower for supplying filtered air through a flexible conduit to the airway of a user in a dusty environment. O'Connor also teaches supplying the filtered air at a greater pressure during inhalation than exhalation. While such personal ventilators have the advantage of being readily attached to an ambulatory person, these devices are not designed to provide respiratory assist to a patient subject to respiratory distress, such as dyspnea. They typically require both the mouth and nose to be covered and do not address themselves to providing portable CPAP delivery.

The present invention is directed toward overcoming one or more of the problems discussed above.

SUMMARY OF THE INVENTION

A first aspect of the invention is a method for treating dyspnea and improving exercise tolerance in an ambulatory patient which includes providing a housing defining a form factor having an air inlet and an air outlet, the housing being sufficiently small to be readily mounted to the body of an ambulatory patient. A pressure generator is provided in the defined form factor of the housing for drawing ambient air in the air inlet and delivering the air at a select pressure greater than ambient pressure to the air outlet. The housing is releasably attached to the body of the patient and the pressurized air is conveyed to the patient airway. Pressure is maintained in the airway, sufficiently greater than the pressure in the airway when the patient is breathing under ambient conditions, to relieve the dyspnea and improve the exercise tolerance of the ambulatory patient. An adjustable control may be provided for varying the select pressure as necessary to prevent the occurrence of dyspnea while minimizing patient discomfort. The air may be filtered before it reaches the air outlet to provide a clean air

supply to the patient, thereby minimizing the risk of introducing irritants to normal respiration.

The method described above may further include the provision of supplemental oxygen to yield a selected elevated concentration of oxygen in the patient gas mixture.

A second aspect of the present invention is an apparatus for treating dyspnea and improving exercise tolerance in an ambulatory patient. The apparatus includes a housing defining a form factor having an air inlet and an air outlet, the housing being sufficiently small to be readily mounted to the body of an ambulatory patient. A pressure generator is located within the defined form factor of the housing for drawing ambient air into the air inlet and delivering the air at a select pressure greater than ambient pressure to the outlet. A strap is provided on the housing for releasably attaching the housing to a patient. A flexible conduit is attached at a proximal end to the air outlet of the housing. A connector attached at a distal end of the conduit connects the distal end of the conduit to the patient airway. A releasable coupling is provided between the strap and the connector so that the connector can be readily accessed by a patient in need of respiratory assist.

Another aspect of the invention is an apparatus for treating dyspnea in an ambulatory patient including a housing defining a form factor having an air inlet and an air outlet, the housing being sufficiently small to be readily mounted to the body of an ambulatory patient. A pressure generator is provided within the defined form factor of the housing for drawing ambient air into the air inlet and delivering the air at a select pressure greater than ambient pressure to the outlet. A strap is provided on the housing for releasably attaching the housing to a patient. A flexible conduit is attached at a proximal end to the air outlet of the housing and a connector is attached at a distal end of the conduit for connecting the distal end of the conduit to the patient airway. A regulator is provided within the form factor in communication with an oxygen supply to provide for delivery of an air oxygen mixture to the outlet at a select elevated level of oxygen concentration.

Yet another aspect of the present invention is an apparatus for delivering pressurized gas to the airway of a patient who is breathing in repeated breathing cycles, each cycle including an inspiration and exhalation phase. The apparatus includes a generator of a flow of gas. A conduit conveys the flow of gas to the airway of a patient. An exhalation vent is provided in fluid communication with the conduit in operative association with the patient airway for passing exhaled gas to the atmosphere. A pressure sensor is in fluid communication with the conduit and the pressure sensor outputs a signal indicative of the pressure in the conduit. A diversion vent has an inlet in fluid communication with the conduit and an outlet to the atmosphere. A diversion valve in fluid communication with the diversion vent selectively permits and prevents a portion of the flow of gas to flow through the diversion vent. A first threshold valve is operatively associated with the diversion vent for permitting outlet of a portion of the flow of gas to the atmosphere when the pressure in the diversion vent is above a select diversion vent pressure. A controller receives the signal from the pressure sensor and is operatively associated with the diversion valve. The controller actuates the valve to permit gas to flow through the diversion vent when the signal indicates a first select rate of increase in pressure and actuates the valve to prevent flow through the diversion vent when the signal indicates a second select rate of decrease in pressure.

The apparatus may also include a second threshold valve in fluid communication with the conduit to maintain a constant pressure in the conduit. The second threshold valve permits outlet of a portion of the flow of gas to the atmosphere when the pressure in the conduit is above a select conduit pressure. Alternatively, where no second threshold valve is provided, a control may be associated with the generator for causing the generator to generate a substantially constant flow rate of gas.

The controller is alternatively made to actuate the diversion valve open after some select period after the controller actuates the diversion valve closed. As a further aspect of the invention, the controller alternatively actuates the diversion valve open for an expiration phase period and actuates the diversion valve closed for an inspiration phase period to provide a breathing cycle for the patient.

The method of treating dyspnea and improving exercise tolerance in an ambulatory patient provides virtually instantaneous relief from the distressful and harmful effects of dyspnea. The method may by administered wherever the patient might be because the respiratory assistance device is readily transportable by an ambulatory patient. Because the method further provides for the introduction of air to a patient at enhanced oxygen concentrations, even where the dyspnea is too severe to be treated effectively by the method, enriched oxygen air is delivered to the patient to ensure adequate supply of oxygen in the patient's limited breaths. The apparatus for treating dyspnea is compact, lightweight and readily carried by even an infirm ambulatory patient. The patient connector is readily available to the patient by virtue of the releasable coupling between the strap and the connector. Because the apparatus is battery powered, an ambulatory patient has complete freedom of movement when using the apparatus. The apparatus may be used with rechargeable batteries, thereby further decreasing the cost of use and facilitating acceptance in the home care market. Finally, the apparatus is capable of providing greater pressure to the lungs during inspiration than during exhalation, so called bi-level positive airway pressure or pressure support ventilation, which minimizes patient discomfort in overcoming the high inspiratory pressure assist during the exhalation period, such as occurs when the CPAP modality is used. Alternatively, the apparatus can provide a short burst of elevated pressure gas during the inception of an inspiration phase, so called burst of positive airway pressure or "BurstPAP". These features are provided in an extremely low cost assembly, making the advantages more readily available to the public.

Additionally the invention provides a method of treating dyspnea and improving exercise tolerance in an ambulatory patient wherein the method comprises:

(a) providing a housing defining a form factor having an air inlet and an air outlet, the housing being sufficiently small to be readily mounted to the body of an ambulatory patient;

(b) providing a pressure generator within the defined form factor of the housing for drawing ambient air in the air inlet and delivering the air at a select pressure greater than an ambient pressure to the air outlet;

(c) releasably attaching the housing to the body of the patient;

(d) conveying the pressurized air to the airway of the patient; and

(e) maintaining a pressure in the airway sufficiently greater than ambient pressure to relieve the dyspnea of the ambulatory patient.

In one embodiment of the invention the method further comprises:

(f) providing means for varying the select pressure; and

(g) varying the select pressure as necessary to prevent occurrence of dyspnea while minimizing patient discomfort.

In another embodiment of the invention the method further comprises in step (b) filtering the air before the air outlet.

In a further embodiment of the invention the method further comprises:

(f) altering the patient when the electric source is sufficiently depleted that the pressure generator will cease operating within a select period of time.

Preferably, the method further comprises:

(f) providing supplemental oxygen between the air inlet and the air outlet to yield a select elevated concentration of oxygen.

In one embodiment of the invention the pressure generator is electrically powered, the method further comprising:

(f) providing an electric source electronically coupled to the pressure generator within the housing.

Advantageously, in the step (e) the airway pressure is maintained at about a first select pressure greater than ambient pressure during inspiration and at about a

second select pressure greater than ambient pressure during exhalation, the first select pressure being greater than the second select pressure.

Advantageously, in the step (e) the first select pressure is maintained at a level providing respiratory assist to the ambulatory patient during at least the inception of inspiration and the second select pressure is maintained at a level which serves to keep the alveoli from collapsing prior to the inception of inspiration.

Ideally, in the step (e) the first select pressure is maintained for only a portion of inspiration at the inception of inspiration.

In one embodiment of the invention the method further comprises:

(f) monitoring the airway pressure and after the pressure drops at a first select rate, maintaining the first select airway pressure and after the pressure rises at a second select rate, maintaining the second select airway pressure.

Further the invention provides apparatus for treating dyspnea and improving exercise tolerance in an ambulatory patient wherein the apparatus comprises:

a housing defining a form factor having an air inlet and an air outlet, the housing being sufficiently small to be readily mounted to the body of an ambulatory patient;

a pressure generator within the defined form factor of the housing for drawing ambient air into the air inlet and delivering the air at a select pressure greater than ambient pressure to the outlet;

a strap on the housing for releasably attaching the housing to the patient;

a flexible conduit attached at a proximal end to the air outlet of the housing;

a connector attached at a distal end of the conduit for connecting the distal end of the conduit to an airway of the patient; and

a releasable coupling between the strap and the connector.

In one embodiment of the invention the pressure generator is electrically powered.

In another embodiment of the invention the apparatus further comprises an electric source within the housing electronically coupled to the pressure generator.

Preferably, the apparatus further comprises a means for introducing oxygen between the air inlet and the air

outlet to deliver air to the outlet at a select elevated concentration of oxygen.

In one embodiment of the invention the connector is a nose piece.

Alternatively, the connector is a mouth piece.

Alternatively, the connector is a face mask.

Alternatively, the connector is a tracheostomy fitting.

Preferably, the apparatus further comprises a means for varying the select pressure delivered to the outlet.

Further the invention provides apparatus for treating dyspnea and improving exercise tolerance in an ambulatory patient wherein the apparatus comprises:

a housing defining a form factor having an air channel with an air inlet and an air outlet, the housing being sufficiently small to be readily mounted to the body of an ambulatory patient;

a pressure generator within the defined form factor of the housing for drawing ambient air into the air inlet and delivering the air at a select pressure greater than ambient pressure to the outlet;

a strap on the housing for releasably attaching

the housing to the patient;

a flexible conduit attached at a proximal end to the air outlet of the housing;

a connector attached at a distal end of the conduit for connecting the distal end of the conduit to an airway of the patient;

an oxygen regulator in fluid communication with the air channel within the form factor;

a means for connecting the oxygen regulator to a supplemental oxygen supply; and

a means coupled to the regulator for controlling the regulator to introduce supplemental oxygen in the air channel to provide a select elevated concentration of oxygen at the air outlet.

Additionally the invention provides apparatus for delivering pressurized gas to the airway of a patient who is breathing in repeated breathing cycles each including an inspiration and an exhalation phase wherein the apparatus comprises:

a generator of a flow of gas;

a conduit for conveying the flow of gas to the airway of the patient at a first select pressure;

an exhalation port in fluid communication with the conduit in operative association with the patient airway for passing exhaled gas to the atmosphere;

a pressure sensor in fluid communication with the

conduit, the pressure sensor outputting a signal indicative of the pressure in the conduit;

a diversion vent having an inlet in fluid communication with the conduit;

a diversion valve in fluid communication with the diversion vent for selectively permitting and preventing a portion of the flow of gas to flow through the diversion vent;

a first threshold valve operatively associated with the diversion vent for permitting outlet of gas to the atmosphere when the pressure in the diversion vent is above a second select pressure; and

a control means receiving the signal from the pressure sensor and operatively associated with the diversion valve, the control means actuating the valve to permit gas flow through the diversion vent when the signal indicates an increase in pressure at a first select rate and actuating the valve to prevent flow through the diversion vent when the signal indicates a decrease in pressure at a second select rate.

In one embodiment of the invention the apparatus further comprises a means associated with the generator for causing the generator to generate a substantially constant flow rate of gas.

In another embodiment of the invention the apparatus

further comprises a second threshold valve in fluid communication with the conduit, the second threshold valve permitting outlet of gas to the atmosphere when the pressure in the conduit is above the first select pressure.

In a still further embodiment of the invention the generator comprises:

an electric motor;

a blower driven by the electric motor,

an electric source coupled to the motor;

a means for producing a blower signal indicative of the blower output; and

a controller receiving the blower signal, the controller being coupled to the electric source to increase or decrease current or voltage to the motor as required to maintain a substantially constant rate of air flow output of the blower.

Preferably, the apparatus further comprises a means operatively associated with the second threshold valve for varying the first select pressure.

Advantageously, the apparatus further comprises a means operatively associated with the first threshold valve for varying the second select pressure.

Ideally, the control means will actuate the valve to permit gas flow through the diversion vent only if the increase in pressure at the first select rate is detected after the pressure sensor has indicated pressure at the first select pressure for longer than a select period.

Preferably, the select period is about 200-300 milliseconds.

Advantageously, the control means will actuate the valve to prevent gas flow through the diversion vent only if the decrease in pressure of the second select rate is detected after the pressure sensor has indicated pressure at the second select pressure for longer than a second select period.

Preferably, the select period is about 200-300 milliseconds.

The invention also provides apparatus for delivering pressurized gas to the airway of a patient who is breathing in repeated breathing cycles each including an inspiration and an exhalation phase wherein the apparatus comprises:

a generator of a flow of gas;

a conduit for conveying the flow of gas to the

airway of the patient at a first select pressure;

an exhalation port in fluid communication with the conduit in operative association with the patient airway for passing exhaled gas to the atmosphere;

a pressure sensor in fluid communication with the conduit, the pressure sensor outputting a signal indicative of the pressure in the conduit;

a diversion vent having an inlet in fluid communication with the conduit;

a diversion valve in fluid communication with the diversion vent for selectively permitting and preventing a portion of the flow of gas to flow through the diversion vent;

a first threshold valve operatively associated with the diversion vent for permitting outlet of gas to the atmosphere when the pressure in the diversion vent is above a second select pressure; and

a control means receiving the signal from the pressure sensor and operatively associated with the diversion valve, the control means actuating the valve to prevent flow through the diversion vent when the signal indicates a decrease in pressure at a first select rate and actuating the valve to permit flow through the diversion vent at the conclusion of a select period after the valve was actuated to prevent flow through the diversion vent.

Preferably, the select period is about equal to the time it takes a patient's chest muscles to assume most of the work of an inspiration phase of a breathing cycle.

Advantageously, the apparatus further comprises a second threshold valve in fluid communication with the conduit, the second threshold valve permitting outlet of gas to the atmosphere when the pressure in the conduit upstream of the second threshold valve is above the first select pressure.

Preferably, the apparatus further comprises a means associated with the generator for causing the generator to generate a substantially constant flow rate of gas.

Advantageously, the apparatus further comprises a means operatively associated with second threshold valve for varying the first select pressure.

Ideally, the apparatus further comprises a means operatively associated with the first threshold valve for varying the second select pressure.

The invention also provides a kit for modifying a respiratory assist device from a continuous airway pressure (CPAP) to a bi-level pressure support assist

device, the respiratory assist device comprising a generator of a substantially consistent first select pressure flow of gas and a conduit for delivering the flow gas to the airway of a patient, wherein the kit comprises:

a diversion vent having an inlet adapted for connection in fluid communication with the conduit of the respiratory assist device;

a pressure sensor in fluid communication with the diversion vent, the pressure sensor outputting a signal indicative of the pressure in the diversion vent;

a diversion valve in fluid communication with the diversion vent downstream of the pressure sensor for selectively permitting and preventing flow of gas through the diversion vent;

a first threshold valve operatively associated with the diversion vent for permitting flow of gas to the atmosphere when the pressure in the diversion vent is above a second select pressure; and

a control means receiving the signal from the pressure sensor and operatively associated with the diversion valve, the control means actuating the valve to permit gas flow through the diversion vent when the signal indicates an increase in pressure at at least a first select rate and actuating the valve to prevent flow through the diversion vent when the signal indicates a decrease in pressure at at least a second

select rate.

The invention also provides a kit comprising a second threshold valve having an inlet adapted for connection in fluid communication with the conduit of the respiratory assist device upstream from the diversion vent, the second threshold valve permitting outlet of gas to the atmosphere when the pressure in the conduit is above the first select pressure.

The invention also provides a kit for modifying a respiratory assist device from a continuous positive airway pressure (CPAP) to a bi-level pressure support assist device, the respiratory assist device comprising a generator of a substantially consistent first select pressure flow of gas and a conduit for delivering the flow gas to the airway of a patient, wherein the kit comprises:

a diversion vent having an inlet adapted for connection in fluid communication with the conduit of the respiratory assist device;

a pressure sensor in fluid communication with the diversion vent, the pressure sensor outputting a signal indicative of the pressure in the diversion vent;

a diversion valve in fluid communication with the diversion vent downstream of the pressure sensor for selectively permitting and preventing flow of gas to

flow through the diversion vent;

a first threshold valve operatively associated with the diversion vent for permitting flow of gas to the atmosphere when the pressure in the diversion vent is above a second select pressure; and

a control means receiving the signal from the pressure sensor and operatively associated with the diversion valve, the control means actuating the valve to prevent flow through the diversion vent when the signal indicates a decrease in pressure at a first select rate and actuating the valve to permit flow through the diversion valve at the conclusion of a select period after the valve was actuated to prevent flow through the diversion vent.

The invention also provides a kit for modifying a respiratory assist device from a continuous positive airway pressure (CPAP) to a bi-level pressure support assist device, the respiratory assist device comprising a generator of a substantially consistent first select pressure flow of gas and a conduit for delivering the flow gas to the airway of a patient, wherein the kit comprises;

a diversion vent having an inlet adapted for connection in fluid communication with the conduit of the respiratory assist device;

a pressure sensor in fluid communication with the

diversion vent, the pressure sensor outputting a signal indicative of the pressure in the diversion vent;

a diversion valve in fluid communication with the diversion vent downstream of the pressure sensor for selectively permitting and preventing a portion of the flow of gas to flow through the diversion vent;

a first threshold valve operatively associated with the diversion vent for permitting flow of gas to the atmosphere when the pressure in the diversion vent is above a second select pressure; and

a control means receiving the signal from the pressure sensor and operatively associated with the diversion valve, the control means actuating the valve to permit gas flow through the diversion vent when the signal indicates an increase in pressure of at least a first select amount above the first select pressure and actuating the valve to prevent flow through the diversion vent when the signal indicates a decrease in pressure of at least a second select amount below the second select pressure.

Further, the invention provides apparatus for delivering pressurized gas to the airway of a patient who is breathing in repeated breathing cycles, each including an inspiration and an exhalation phase, wherein the apparatus comprises:

a generator of a flow of gas;

a conduit for conveying the flow of gas to the airway of the patient at a first select pressure;

an exhalation port in fluid communication with the conduit in operative association with the patient airway for passing exhaled gas to the atmosphere;

a pressure sensor in fluid communication with the conduit, the pressure sensor outputting a signal indicative of the pressure in the conduit;

a diversion vent having an inlet in fluid communication with the conduit;

a diversion valve in fluid communication with the diversion vent for selectively permitting and preventing flow of gas through the diversion vent;

a first threshold valve operatively associated with the diversion vent for permitting outlet of gas to the atmosphere when the pressure in the diversion vent is above a second select pressure; and

a control means receiving the signal from the pressure sensor and operatively associated with the diversion valve, the control means actuating the valve to permit gas flow through the diversion vent when the signal indicates an increase in pressure at least a first select amount above the first select pressure and actuating the valve to prevent flow through the diversion vent when the signal indicates a decrease in pressure of at least a second select amount below the second select pressure.

Brief Description of the Drawings

Fig. 1 is a perspective view of an apparatus for treating dyspnea in an ambulatory patient in accordance with the present invention;

Fig. 2 is a perspective view of the apparatus of Fig. 1 worn on the side of a patient in a ready position;

Fig. 3 is a perspective view of the apparatus of Fig. 1 worn on the side of a patient in use;

Fig. 4 is a perspective view of the apparatus of Fig. 1 illustrated on the back of a patient;

Fig. 5 is a functional block diagram of the components of the apparatus of Fig. 1;

Fig. 6 is a functional block diagram of the control circuit of Fig. 5;

Fig. 7 is a schematic representation of the apparatus for relieving dyspnea in an ambulatory patient of Fig. 1;

Fig. 8 is an alternate embodiment of Fig. 7 including a schematic illustration of an apparatus for enabling air to be provided to the patient at different pressures;

Fig. 9 is an alternate embodiment of the apparatus of Fig. 8; and

Fig. 10 is a graph of bi-level pressure versus time generated during a breathing cycle, with P_{high} being the inspiration pressure level and P_{low} being the exhalation pressure level.

Detailed Description of the Preferred Embodiment

The portable respirator or apparatus 10 for relieving dyspnea in an ambulatory patient is illustrated in perspective view in Fig. 1. The apparatus consists of a housing 12 which defines an internal form factor. The housing 12 is sufficiently small to be readily worn by a patient as illustrated in Figs. 2-4. A dual element mounting strap 14 is attached to the housing so that the housing may be mounted to a patient.

On the face of the housing 12 is an air inlet 18 and on top is an air outlet 20. Air flow from the air outlet 20 is passed through a flexible conduit 22 to a mouth piece 24, which can be any suitable patient connector. Other patient connectors which may be used in lieu of a mouth piece include a mask, a nose piece, a nasal cannula, an endotracheal tube, a tracheostomy fitting or any other suitable appliance for interfacing

between a source of breathing gas and the airway of the patient consistent with the intended purpose of the apparatus 10.

The mouth piece 24 includes a suitable exhaust port, indicated schematically at 26. The exhaust port exhausts breathing gases during expiration and is preferably configured to allow build up of suitable pressure to provide the desired respiratory assist described in greater detail below. Such exhaust ports are known in the art and the choice and location of the precise exhaust port to be used with this invention is considered to be a matter of design choice.

A releasable coupling 28 is located between the strap 14 and proximate to the distal end of a flexible conduit 22. As illustrated in Fig. 1, the releasable coupling comprises a tab 30 affixed to the mouth piece 24. Alternatively, the tab 30 may be located on the conduit 22 proximate the mouth piece 24. The releasable coupling 28 also includes a receptor 32 mounted on the strap 14 into which the tab 30 can be slidably engaged. Other releasable couplings such as a VELCRO loop and hook fastener may also be suitable.

The housing 12 also includes on its exterior surface a pressure control switch 34, an indicator light 36 and an oxygen concentration control panel 38.

As illustrated in Figs. 2, 3 and 4, the housing 12 may be mounted either to the side of patient or to a patient's back using the mounting strap 14. In either instance, the releasable coupling 28 is located on the strap 14 on the patient's chest such that the mouth piece 24 is conveniently and readily accessible by a patient 39.

The components contained within the housing 12 are illustrated in block form in Figs. 5 and 6. Air is driven between the air inlet 18 and the air outlet 20 through an air flow channel 40 by a blower 41 consisting of a DC electric motor 42 and an impeller 44. A filter 46 is snap fit to the housing 12 so that particulates are removed as air indicated by the arrows 48 enters the inlet 18. The motor 42 is coupled to a control circuit 50 at 51. As described in greater detail with regard to Fig. 6, the control circuit 50 processes inputs from the pressure control 34, sensors associated with the motor and the control panel 38 to maintain operation of the apparatus 10. Also contained within the

housing 12 is a DC power source or battery 52. The battery is coupled at 53 to the control circuit 50 which in turn delivers electric energy under pulse with modulation, to the DC electric motor 42 via the coupling 51.

A regulator 56 has an inlet 57 and an outlet 58, the outlet 58 being in fluid communication with the airflow channel 40 between the inlet 18 and the outlet 20 of the housing 12. As shown, the regulator outlet 58 is upstream from the impeller 44. The regulator outlet could alternatively bleed into the airflow channel upstream from the impeller 44. The regulator 56 is electrically coupled to the control circuit 50 at 59 so that operation of the regulator 56 may be controlled by the control circuit 50. The inlet 57 may be connected in fluid communication with a remote oxygen supply 60. With the inlet 57 connected to the oxygen supply 60, supplemental oxygen may be provided in a select concentration ranging from 21% to near 100%.

The control circuit 50 is shown in greater detail in the functional block diagram of Fig. 6. The control circuit 50 includes a power stage 70 for delivering three phase power to the windings of the motor 42 through the electrical conduit 72. A current detector 74 is in electrical communication with the conduit 72 and delivers a signal indicative of the current in the conduit 72 to the control stage via the connection 76. A Hall sensor 78 is coupled at 80 to the output shaft 82 of the motor 42 and sends a signal via the connection 84 to the control stage 88, which may be a microprocessor. The control stage 88 contains logical circuitry or is programmed to receive inputs from the current detector 74 and the Hall sensor 78 along with the pressure control 34 which enables it to control the voltage delivered to the power stage 70 by connection 90 so that air is delivered to the outlet 20 at a select pressure. The control stage 88 also includes logical circuitry for controlling to what extent oxygen is introduced by the regulator 56 through the outlet 58 into the air flow channel 40 between the inlet 18 and the outlet 20. The control stage 88 further monitors the power output of the battery 52 and displays an indication of the battery level by the indicator light 36. The indicator light 36 preferably includes a number of illuminated panels. As power is consumed, the lights serially turn off to apprize the user of the approximate power remaining in the battery. When the

control stage 88 determines that the battery level is insufficient to support sustained operation, an indicator alerts the patient. The indicator could be an audible or visible alarm.

In use, a patient prone to dyspnea or requiring improved exercise tolerance, such as a patient suffering from COPD, mounts the housing 12 to his body using the strap 14 in either manner illustrated in Figs. 2-4. Generally the configuration illustrated in Figs. 2 and 3 is preferred because of ease of access to the controls on the housing. The mouth piece is thus conveniently located on the user's chest. Should the user begin experiencing breathlessness, the mouth piece can be readily brought into operative engagement in the mouth of the user and the pressure control 34 can be turned on to begin delivering pressurized air to the outlet 20 and the patient's airway. The delivered air at elevated pressure relieves dyspnea by reducing the patient's work of breathing. This is accomplished by the air at elevated pressure keeping open alveoli which otherwise collapse, such as happens in emphysema. In this manner, the patient receives air as soon as the breath effort is initiated. The patient uses the pressure control 34 to allow air to be delivered at a select pressure to the outlet 20 and ultimately the patient's airway which alleviates the dyspnea, thereby relieving patient distress. If required, supplemental oxygen is available through adjustment of the control panel 38.

Fig. 7 illustrates schematically the flow of air in the apparatus 10 for relieving dyspnea. Air is conveyed from the air outlet 20 of the housing 12 through the flexible conduit 22 to patient mouth piece 24. The mouth piece 24 has an exhaust port 26. In operation, with the mouth piece received in the mouth of a patient and the blower operating inside the housing, pressurized air flows to the mouth piece. The air is maintained at a substantially constant pressure by keeping the gas flow rate substantially constant by controlling blower output and venting the gas flow through the exhaust port 26. The blower output is kept substantially constant by monitoring the rate of rotation of the output shaft of the motor and adjustment of the current or supplied to the motor to keep the rate of rotation of the output shaft substantially constant (see

discussion above). The apparatus is configured to provide air at between 0-15 cm H_2O above ambient air pressure, as selected by the patient.

Fig. 8 illustrates schematically an alternate embodiment of the apparatus for relieving dyspnea in an ambulatory patient 10'. For simplicity, like elements will have the same reference numeral as the foredescribed embodiment, only including a prime. The embodiment 10' is an apparatus for providing a flow of air at a first select pressure greater than ambient pressure during inspiration and a second select pressure greater than ambient during exhalation, the first select pressure being greater than the second select pressure. As in the embodiment illustrated in Fig. 7, this embodiment includes a blower housing 12' having a conduit 22' connected at the outlet 20' with the conduit 22' terminating at the mouth piece 24'. The mouth piece 24' includes an exhaust port 26'. The first select pressure is maintained by keeping the blower output substantially constant, as described above with reference to Fig. 7. Of course, the voltage or current to the blower motor may be varied to vary the first select pressure.

In this embodiment, a diversion vent 110 is in fluid communication with the conduit 22'. The diversion vent 110 as illustrated consists of a diversion conduit 112 which terminates at a positive end expiratory pressure ("PEEP") valve 114. As is readily understood by those skilled in the art, the PEEP valve functions as a threshold valve which vents air through the outlet 116 when the pressure in the diversion conduit 112 exceeds some select threshold corresponding to the second select pressure. In this application, the threshold pressure would be slightly above ambient pressure to provide a level of pressure to maintain lung alveoli open to a greater extent than under ambient pressure. Typically this pressure would be about 1-5 cm H_2O above ambient pressure. The PEEP valve 114 is preferably adjustable to vary the second select pressure. One form of a variable PEEP valve is described in Rapoport, U.S. Patent No. 5,065,756. A diversion valve 118 is in fluid communication with the diversion vent. The diversion valve selectively permits and prevents a flow of gas through the diversion vent 110 by opening or closing the diversion conduit 112 at the seat 120. More particularly, in the embodiment illustrated in Fig. 8, the diversion valve 118 pneumatically actuates a

mushroom valve 122. An exhaust port 124 is provided in the pneumatic diversion valve 118 to vent the gas used to drive the mushroom valve 122 into abutment with the seat 120. In order to provide gas to actuate the mushroom valve 122, the pneumatic diversion valve 118 is in fluid communication through the diversion valve conduit 126 with the conduit 22'.

Also in fluid communication with the conduit 22' through a pressure sensor conduit 128 is a pressure sensor 130. The pressure sensor 130 is in turn electrically coupled to the controller 132 by connection 134. Connection 136 maintains the controller 132 in electric communication with the pneumatic diversion valve 118.

In operation, the embodiment illustrated in Fig. 8 functions as follows. The blower 12' provides a flow of gas at a substantially constant rate to the mask 24'. The exhaust port 26 allows the pressure in the conduit 22' to then remain substantially constant at the first select pressure. During an inhalation phase of a breathing cycle, the pneumatic diversion valve 118 would be seated so as to prevent flow of air through the diversion conduit 112. At the start of exhalation, the pressure in the conduit 22' would increase rapidly, as illustrated in phantom lines in Fig. 10. The pressure sensor would detect this rise in pressure and send a signal indicating this rise in pressure to the controller 132. If the rate at which pressure rises (i.e. the pressure slope) is greater than a select rate (e.g. 10 cm H_2O/sec) the controller 132 will then send a signal to the pneumatic diversion valve 118 to actuate, whereby an internal valve cuts off gas flow from the diversion valve conduit 126 and allows the mushroom valve 122 to exhaust the actuating air through the exhaust port 124. Preferably, the controller will only actuate the pneumatic diversion valve if the positive pressure slope is detected after a select period of time (e.g., 200-300 milliseconds) has elapsed in the inspiratory phase. In other words, pressure has been at P_{high} for 200-300 milliseconds in Fig. 10. In this manner, false positives are minimized. The sudden increase in pressure is indicated in the phantom line 150 of Fig. 10 at 152. Virtually simultaneously, the pressurized gas in the diversion conduit 112 will unseat the mushroom valve from the seat 120. A spring or the like may also be provided to bias the mushroom valve open. Thus, the flow of air

through the diversion conduit 112 to the threshold valve 114 will be enabled. If the pressure in the diversion conduit 112 exceeds the threshold pressure of the threshold valve, excess gas will be vented to the atmosphere through the exhaust outlet 116. The threshold valve 114 is designed to prevent flow of air at a pressure above ambient pressure but considerably below the pressure in the conduit 22' when the mushroom valve 122 is seated (i.e., the second select pressure). Thus, the pressure in the diversion conduit 112 as well as the conduit 22' decreases and the amount of the air delivered to the patient through the mask 24' diminishes significantly, easing the opposition to the patient exhaling.

Upon the conclusion of an expiration phase of a breathing cycle, the pressure in the conduit 22' will spike downward due to patient triggering as indicated in at 154 Fig. 10. If the rate at which the pressure drops (i.e., the pressure slope) exceeds a select rate (again, about 10 cm H_2O/sec), the controller 132 will determine that inspiration has begun and a signal will be sent to the pneumatic diversion valve 118 causing actuation of valving within the pneumatic diversion valve 118 which causes flow of air through the diversion valve conduit 126 to actuate and extend the mushroom valve 122 into contact with the seat 120. Simultaneously, of course, flow through the exhaust port 124 is prevented. The conduit 22' therefore quickly repressurizes to the initial (i.e., first select pressure or P_{high}) pressure thereby enhancing the respiratory assist available to the patient during inspiration. Preferably, the controller will only actuate the pneumatic diversion valve if the drop in pressure occurs after exhalation has been maintained for a select period (e.g., 200-300 milliseconds) to minimize false positives. In Fig. 10, the exhalation phase would correspond to P_{low}.

As a back-up procedure to actuate the pneumatic diversion valve in the event exhalation is occurring but at an insufficient rate to actuate the pneumatic valve, the controller will actuate the pneumatic valve open if at the end of inspiration the pressure rises some select amount over the first select pressure, typically 2 cm H_2O. Likewise, at the end of an exhalation phase if the triggering rate of pressure decrease is

not detected, the controller will actuate the pneumatic valve closed when the pressure drops some select amount (e.g., 2 cm H_2O) below the second select pressure.

A phantom line 139 in Fig. 8 represents schematically that the enclosed elements could be part of a kit for installation in fluid communication with the conduit 22'. The phantom line represents a housing for the kit. A diversion vent 110 is connected in fluid communication with the conduit 22' by a suitable connector between the diversion conduit 112 and the conduit 22'.

Fig. 9 illustrates a modification of the embodiment 10' illustrated in Fig. 8. This modification provides a threshold or PEEP valve 140 in fluid communication with the conduit 22' upstream from the pressure sensor 130 and the diversion vent 110. The threshold valve 140 is configured to vent through the outlet 142 any airflow from the blower12' in excess of that required to maintain pressure in the conduit 22' at a select pressure, that is, the first select or inspiratory pressure. The advantage of using the threshold valve 140 is that it is no longer necessary to maintain the output of the blower 12' substantially constant in order to maintain a constant pressure in the conduit 22'. All that is required is that the blower maintain sufficient excess airflow to the outlet 20' so that airflow in excess of that necessary to maintain the select pressure in the conduit 22' can be vented through the outlet 142. The threshold valve 140 therefore affords a more precise and lower cost apparatus to maintain a constant pressure in the conduit 22' than that afforded by monitoring of the blower output described above with reference to Fig. 7. As with the threshold valve 114, the threshold valve 140 is preferably adjustable to vary the first select pressure. This configuration is otherwise identical to that described above with regard to Fig. 8.

A phantom line 143 in Fig. 9 represents schematically that the enclosed elements could be part of a kit for installation in fluid communication with the conduit 22'. The phantom line 143 represents a housing for the kit. The threshold valve 140 and is connected in fluid communication with the conduit 22' and downstream of the threshold valve 140 and is in fluid communication with both the conduit 22' and the diversion vent 110, as illustrated. A fluid tight seal is maintained by a suitable connector.

Both the embodiments illustrated in Figs. 8 and 9 include a pneumatically actuated diversion valve 118. Those skilled in the art would readily recognize that other valve structures are suitable for functioning as the diversion valve 118. For example, the mushroom valve 122 could be actuated by conventional electric solenoid, thereby eliminating the need for diversion valve conduit valve 126 and the exhaust port 124 of the pneumatically actuated diversion valve.

In the embodiments just described, the diversion valve 118 is actuated by detection in a change of the slope of the pressure curve 150 within the conduit 22', as illustrated in Fig. 10. In some instances, it may be advantageous to provide respiratory assist only during the initial period of the inspiration phase of a breathing cycle. Recent studies have shown that the diaphragm plays its most important role in the early phases of inspiration, whereas the chest wall muscles perform most of the work during the rest of the inspiration cycle. Thus, a more palliative mode of treatment employs the higher respiratory assist pressure only for a small portion of the inspiration phase necessary to relieve work of the diaphragm, and hence relieve dyspnea resulting from diaphragmatic fatigue, while diminishing the pressure in the conduit 22' to only slightly greater than ambient during the remainder of the inspiration phase where the chest muscles are assisting in breathing and during the exhalation phase. In order to provide this function, the controller would actuate the diversion valve 118' closed for only a select assist period upon detecting the start of the inspiration phase of a breathing cycle. While this period may vary from patient to patient, it is typically in the range of 0-300 milliseconds. The controller would therefore be programmed not to actuate the valve open at the detection of the beginning of an exhalation phase of a breathing cycle, but at the end of the select period.

The configuration 10' could also be used for pressure control ventilation in a patient incapable of spontaneous breathing. In such an embodiment, the controller 132 would alternately actuate the diversion valve to prevent gas flow through the diversion valve for a first select period of time and actuate the diversion valve to prevent gas flow through the diversion valve for a second select period of time, the first and

second select periods of times corresponding to a desired period of inspiration and a desired period of exhalation of a breathing cycle, respectively. Typically these periods range from 0.2-3 seconds.

The embodiments discussed above provide a simple pneumatic configuration to enable a generator of a constant gas flow such as a blower 12' to be used to provide differing levels of pressure assist during the inspiration and exhalation phases of a breathing cycle. Other sources of gas flow, such as compressed gas, could be used as the flow generator. In this manner, the pressure of the gas provided to the patient during exhalation can be reduced significantly from that provided during inspiration to enhance patient comfort and decrease the amount of work a patient must do in order to exhale properly. Use of the threshold or PEEP valve 140 in the embodiment illustrated in Fig. 9 eliminates the need for precise controls on the output of the blower 12', which can further serve to reduce the cost of the apparatus while still providing the many advantages discussed above. Not only can this system be used to provide bi-level pressure support ventilation, it can also be programed to provide a burst of air for only a short period following the beginning of inspiration, thereby leaving the patient's chest muscles to complete the inspiration phase. Finally, the controller could also be programed so as to provide pressure control ventilation to a patient unable to breath spontaneously.

CLAIMS

1. A method of treating dyspnea and improving exercise tolerance in an ambulatory patient characterised in that the method comprises:

(a) providing a housing (12) defining a form factor having an air inlet (18) and an air outlet (20), the housing (12) being sufficiently small to be readily mounted to the body of an ambulatory patient (39);

(b) providing a pressure generator (41) within the defined form factor of the housing (12) for drawing ambient air in the air inlet (18) and delivering the air at a select pressure greater than an ambient pressure to the air outlet (20);

(c) releasably attaching the housing (12) to the body of the patient (39);

(d) conveying the pressurized air to the airway of the patient; and

(e) maintaining a pressure in the airway sufficiently greater than ambient pressure to relieve the dyspnea of the ambulatory patient.

2. A method as claimed in Claim 1 further comprising:

(f) providing means for varying the select pressure; and

(g) varying the select pressure as necessary to prevent occurrence of dyspnea while minimizing

patient discomfort.

3. A method as claimed in Claim 1 or 2 further comprising in step (b) filtering the air before the air outlet (20).

4. A method as claimed in any preceding claim further comprising:

(f) alerting the patient when the electric source is sufficiently depleted that the pressure generator will cease operating within a select period of time.

5. A method as claimed in any preceding claim further comprising:

(f) providing supplemental oxygen between the air inlet (18) and the air outlet (20) to yield a select elevated concentration of oxygen.

6. A method as claimed in any preceding claim wherein the pressure generator (41) is electrically powered, the method further comprising:

(f) providing an electric source (52) electronically coupled to the pressure generator (41) within the housing (12).

7. A method as claimed in any preceding claim wherein

in step (e) the airway pressure is maintained at about a first select pressure greater than ambient pressure during inspiration and at about a second select pressure greater than ambient pressure during exhalation, the first select pressure being greater than the second select pressure.

8. A method as claimed in Claim 7 wherein in step (e) the first select pressure is maintained at a level providing respiratory assist to the ambulatory patient during at least the inception of inspiration and the second select pressure is maintained at a level which serves to keep the alveoli from collapsing prior to the inception of inspiration.

9. A method as claimed in Claim 8 wherein in step (e) the first select pressure is maintained for only a portion of inspiration at the inception of inspiration.

10. A method as claimed in any of Claims 7 to 9 further comprising:

(f) monitoring the airway pressure and after the pressure drops at a first select rate, maintaining the first select airway pressure and after the pressure rises at a second select rate, maintaining the second select airway pressure.

11. Apparatus (10) for treating dyspnea and improving exercise tolerance in an ambulatory patient characterised in that the apparatus comprises:

a housing (12) defining a form factor having an air inlet (18) and an air outlet (20), the housing (12) being sufficiently small to be readily mounted to the body of an ambulatory patient (39);

a pressure generator (41) within the defined form factor of the housing (12) for drawing ambient air into the air inlet (18) and delivering the air at a select pressure greater than ambient pressure to the outlet (20);

a strap (14) on the housing (12) for releasably attaching the housing (12) to the patient (39);

a flexible conduit (22) attached at a proximal end to the air outlet (20) of the housing (12);

a connector (24) attached at a distal end of the conduit (22) for connecting the distal end of the conduit (22) to an airway of the patient (39); and

a releasable coupling (28) between the strap (14) and the connector (24).

12. Apparatus as claimed in Claim 11 wherein the pressure generator (41) is electrically powered.

13. Apparatus as claimed in Claim 12 further comprising an electric source (52) within the housing

(12) electronically coupled to the pressure generator (41).

14. Apparatus of Claim 11 further comprising a means (56) for introducing oxygen between the air inlet (18) and the air outlet (20) to deliver air to the outlet (20) at a select elevated concentration of oxygen.

15. Apparatus as claimed in any of Claims 11 to 14 wherein the connector (24) is a nose piece.

16. Apparatus as claimed in any of Claims 11 to 14 wherein the connector (24) is a mouth piece.

17. Apparatus as claimed in any of Claims 11 to 14 wherein the connector (24) is a face mask.

18. Apparatus as claimed in any of Claims 11 to 14 wherein the connector (24) is a tracheostomy fitting.

19. Apparatus as claimed in any of Claims 11 to 18 further comprising a means (34) for varying the select pressure delivered to the outlet (20).

20. Apparatus for treating dyspnea and improving exercise tolerance in an ambulatory patient characterised in that the apparatus comprises:

a housing (12) defining a form factor having an air channel (40) with an air inlet (18) and an air outlet (20), the housing (12) being sufficiently small to be readily mounted to the body of an ambulatory patient (39);

a pressure generator (41) within the defined form factor of the housing (12) for drawing ambient air into the air inlet (18) and delivering the air at a select pressure greater than ambient pressure to the outlet (20);

a strap (14) on the housing (12) for releasably attaching the housing (12) to the patient (39);

a flexible conduit (22) attached at a proximal end to the air outlet (20) of the housing (12);

a connector (24) attached at a distal end of the conduit (22) for connecting the distal end of the conduit (22) to an airway of the patient (39);

an oxygen regulator (56) in fluid communication with the air channel (40) within the form factor.

a means (57) for connecting the oxygen regulator (56) to a supplemental oxygen supply; and

a means (50) coupled to the regulator (56) for controlling the regulator (56) to introduce supplemental oxygen in the air channel (40) to provide a select elevated concentration of oxygen at the air outlet (20).

21. Apparatus for delivering pressurized gas to the airway of a patient who is breathing in repeated breathing cycles each including an inspiration and an exhalation phase characterised in that the apparatus comprises:

a generator (41) of a flow of gas;

a conduit (22) for conveying the flow of gas to the airway of the patient at a first select pressure;

an exhalation port (26) in fluid communication with the conduit in operative association with the patient airway for passing exhaled gas to the atmosphere;

a pressure sensor (130) in fluid communication with the conduit (22), the pressure sensor (130) outputting a signal indicative of the pressure in the conduit (22);

a diversion vent (110) having an inlet (112) in fluid communication with the conduit (22);

a diversion valve (118) in fluid communication with the diversion vent (110) for selectively permitting and preventing a portion of the flow of gas to flow through the diversion vent (110);

a first threshold valve (114) operatively associated with the diversion vent (110) for permitting outlet of gas to the atmosphere when the pressure in the diversion vent (110) is above a second select pressure; and

a control means (132) receiving the signal from the pressure sensor (130) and operatively associated with the diversion valve (118), the control means (132) actuating the valve (118) to permit gas flow through the diversion vent (110) when the signal indicates an increase in pressure at a first select rate and actuating the valve (118) to prevent flow through the diversion vent (110) when the signal indicates a decrease in pressure at a second select rate.

22. Apparatus of Claim 21 further comprising a means (74, 78, 88) associated with the generator (41) for causing the generator (41) to generate a substantially constant flow rate of gas.

23. Apparatus as claimed in Claim 21 or 22 further comprising a second threshold valve (118, 120) in fluid communication with the conduit (22), the second threshold valve (118, 120) permitting outlet of gas to the atmosphere when the pressure in the conduit (22) is above the first select pressure.

24. Apparatus as claimed in any of Claims 21 to 23 wherein the generator (41) comprises:

an electric motor (42);

a blower (44) driven by the electric motor (42);

an electric source (52) coupled to the motor (42);

a means (74, 78) for producing a blower signal indicative of the blower output; and

a controller (88) receiving the blower signal, the controller (88) being coupled to the electric source (52) to increase or decrease current or voltage to the motor (42) as required to maintain a substantially constant rate of air flow output of the blower (44).

25. Apparatus as claimed in Claim 23 further comprising a means (132) operatively associated with the second threshold valve (118, 120) for varying the first select pressure.

26. Apparatus of Claim 21 further comprising a means operatively associated with the first threshold valve (114) for varying the second select pressure.

27. Apparatus as claimed in any of Claims 21 to 26 wherein the control means (132) will actuate the valve (118) to permit gas flow through the diversion vent (110) only if the increase in pressure at the first select rate is detected after the pressure sensor (130) has indicated pressure at the first select pressure for longer than a select period.

28. Apparatus as claimed in Claim 28 wherein the select period is about 200-300 milliseconds.

29. Apparatus as claimed in any of Claims 21 to 28 wherein the control means (132) will actuate the valve (118) to prevent gas flow through the diversion vent (110) only if the decrease in pressure of the second select rate is detected after the pressure sensor (130) has indicated pressure at the second select pressure for longer than a second select period.

30. Apparatus of Claim 29 wherein the select period is about 200-300 milliseconds.

31. Apparatus for delivering pressurized gas to the airway of a patient who is breathing in repeated breathing cycles each including an inspiration and an exhalation phase characterised in that the apparatus comprises:

a generator (41) of a flow of gas;

a conduit (22) for conveying the flow of gas to the airway of the patient (39) at a first select pressure;

an exhalation port (26) in fluid communication with the conduit (22) in operative association with the patient airway for passing exhaled gas to the atmosphere;

a pressure sensor (130) in fluid communication with the conduit (22), the pressure sensor (130) outputting a signal indicative of the pressure in the

conduit (22);

a diversion vent (110) having an inlet (112) in fluid communication with the conduit (22);

a diversion valve (118) in fluid communication with the diversion vent (110) for selectively permitting and preventing a portion of the flow of gas to flow through the diversion vent (110);

a first threshold valve (114) operatively associated with the diversion vent (110) for permitting outlet of gas to the atmosphere when the pressure in the diversion vent (110) is above a second select pressure; and

a control means (132) receiving the signal from the pressure sensor (130) and operatively associated with the diversion valve (118), the control means (132) actuating the valve (118) to prevent flow through the diversion vent (110) when the signal indicates a decrease in pressure at a first select rate and actuating the valve (118) to permit flow through the diversion vent (110) at the conclusion of a select period after the valve (118) was actuated to prevent flow through the diversion vent (110).

32. Apparatus as claimed in Claim 31 wherein the select period is about equal to the time it takes a patient's chest muscles to assume most of the work of an inspiration phase of a breathing cycle.

33. Apparatus as claimed in Claim 31 or 32 further comprising a second threshold valve (118, 120) in fluid communication with the conduit (22), the second threshold valve (118, 120) permitting outlet of gas to the atmosphere when the pressure in the conduit (22) upstream of the second threshold valve (118, 120) is above the first select pressure.

34. Apparatus as claimed in any of Claims 31 to 33 further comprising a means (74, 78, 88) associated with the generator (41) for causing the generator (41) to generate a substantially constant flow rate of gas.

35. Apparatus of Claim 33 further comprising a means operatively associated with second threshold valve (118, 120) for varying the first select pressure.

36. Apparatus as claimed in any of Claims 31 to 35 further comprising a means operatively associated with the first threshold valve (114) for varying the second select pressure.

37. A kit for modifying a respiratory assist device from a continuous positive airway pressure (CPAP) to a bi-level pressure support assist device, the respiratory assist device comprising a generator of a substantially consistent first select pressure flow of

gas and a conduit for delivering the flow gas to the airway of a patient, characterised in that, the kit comprises:

a diversion vent (110) having an inlet (112) adapted for connection in fluid communication with the conduit (22) of the respiratory assist device;

a pressure sensor (130) in fluid communication with the diversion vent (110), the pressure sensor (130) outputting a signal indicative of the pressure in the diversion vent (110);

a diversion valve (118) in fluid communication with the diversion vent (110) downstream of the pressure sensor (130) for selectively permitting and preventing flow of gas through the diversion vent (110);

a first threshold valve (114) operatively associated with the diversion vent (110) for permitting flow of gas to the atmosphere when the pressure in the diversion vent (110) is above a second select pressure; and

a control means (132) receiving the signal from the pressure sensor (130) and operatively associated with the diversion valve (118), the control means (132) actuating the valve (118) to permit gas flow through the diversion vent (110) when the signal indicates an increase in pressure at at least a first select rate and actuating the valve (118) to prevent flow through

the diversion vent (110) when the signal indicates a decrease in pressure at at least a second select rate.

38. A kit as claimed in Claim 37 further comprising a second threshold valve (140) having an inlet adapted for connection in fluid communication with the conduit (22) of the respiratory assist device upstream from the diversion vent (110), the second threshold valve (140) permitting outlet (142) of gas to the atmosphere when the pressure in the conduit (22) is above the first select pressure.

39. A kit for modifying a respiratory assist device from a continuous positive airway pressure (CPAP) to a bi-level pressure support assist device, the respiratory assist device comprising a generator of a substantially consistent first select pressure flow of gas and a conduit for delivering the flow gas to the airway of a patient, characterised in that the kit comprises:

a diversion vent (110) having an inlet (112) adapted for connection in fluid communication with the conduit (22) of the respiratory assist device;

a pressure sensor (130) in fluid communication with the diversion vent (110), the pressure sensor (130) outputting a signal indicative of the pressure in the diversion vent (110);

a diversion valve (118) in fluid communication with the diversion vent (110) downstream of the pressure sensor (130) for selectively permitting and preventing flow of gas to flow through the diversion vent (110);

a first threshold valve (114) operatively associated with the diversion vent (110) for permitting flow of gas to the atmosphere when the pressure in the diversion vent (110) is above a second select pressure; and

a control means (132) receiving the signal from the pressure sensor (130) and operatively associated with the diversion valve (118), the control means (132) actuating the valve (118) to prevent flow through the diversion vent (110) when the signal indicates a decrease in pressure at a first select rate and actuating the valve (118) to permit flow through the diversion valve at the conclusion of a select period after the valve (118) was actuated to prevent flow through the diversion vent (110).

40. A kit for modifying a respiratory assist device from a continuous positive airway pressure (CPAP) to a bi-level pressure support assist device, the respiratory assist device comprising a generator of a substantially consistent first select pressure flow of gas and a conduit for delivering the flow gas to the

airway of a patient, characterised in that the kit comprises:

a diversion vent (110) having an inlet (112) adapted for connection in fluid communication with the conduit (22) of the respiratory assist device;

a pressure sensor (130) in fluid communication with the diversion vent (110), the pressure sensor (130) outputting a signal indicative of the pressure in the diversion vent (110);

a diversion valve (118) in fluid communication with the diversion vent (110) downstream of the pressure sensor (130) for selectively permitting and preventing a portion of the flow of gas to flow through the diversion vent (110);

a first threshold valve (114) operatively associated with the diversion vent (110) for permitting flow of gas to the atmosphere when the pressure in the diversion vent (110) is above a second select pressure; and

a control means (132) receiving the signal from the pressure sensor (130) and operatively associated with the diversion valve (118), the control means (132) actuating the valve (118) to permit gas flow through the diversion vent (110) when the signal indicates an increase in pressure of at least a first select amount above the first select pressure and actuating the valve (118) to prevent flow through the diversion vent (110)

when the signal indicates a decrease in pressure of at least a second select amount below the second select pressure.

41. An apparatus for delivering pressurized gas to the airway of a patient who is breathing in repeated breathing cycles, each including an inspiration and an exhalation phase, characterised in that the apparatus comprises:

a generator (41) of a flow of gas;

a conduit (22) for conveying the flow of gas to the airway of the patient (39) at a first select pressure.

an exhalation port (26) in fluid communication with the conduit (22) in operative association with the patient airway for passing exhaled gas to the atmosphere;

a pressure sensor (130) in fluid communication with the conduit (22), the pressure sensor (130) outputting a signal indicative of the pressure in the conduit (22);

a diversion vent (110) having an inlet in fluid communication with the conduit (22);

a diversion valve (118) in fluid communication with the diversion vent (110) for selectively permitting and preventing flow of gas through the diversion vent (110);

a first threshold valve (114) operatively associated with the diversion vent (110) for permitting outlet of gas to the atmosphere when the pressure in the diversion vent is above a second select pressure; and

a control means (132) receiving the signal from the pressure sensor (130) and operatively associated with the diversion valve (118), the control means (132) actuating the valve (118) to permit gas flow through the diversion vent (110) when the signal indicates an increase in pressure at least a first select amount above the first select pressure and actuating the valve (118) to prevent flow through the diversion vent (110) when the signal indicates a decrease in pressure of at least a second select amount below the second select pressure.

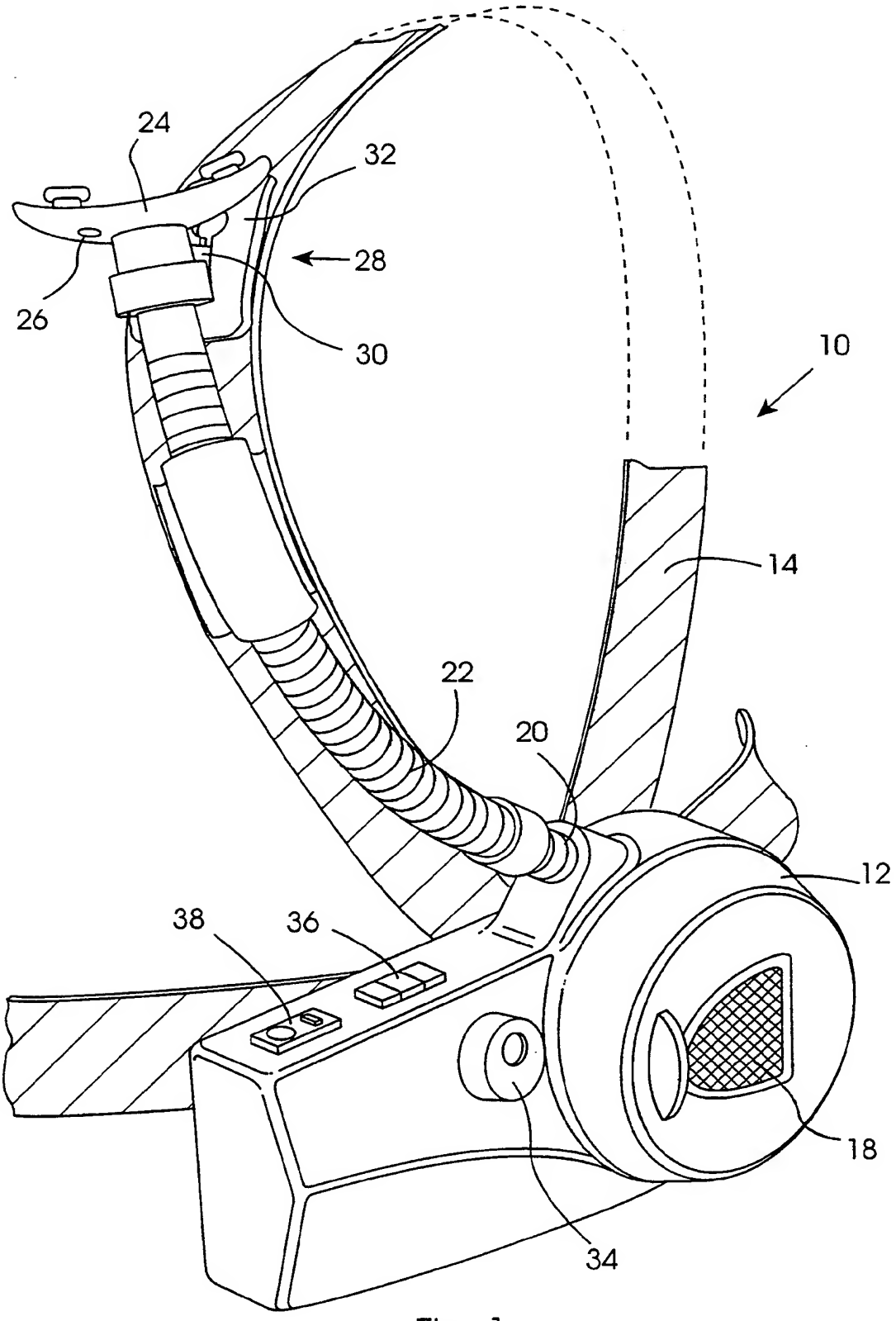

Fig. 1

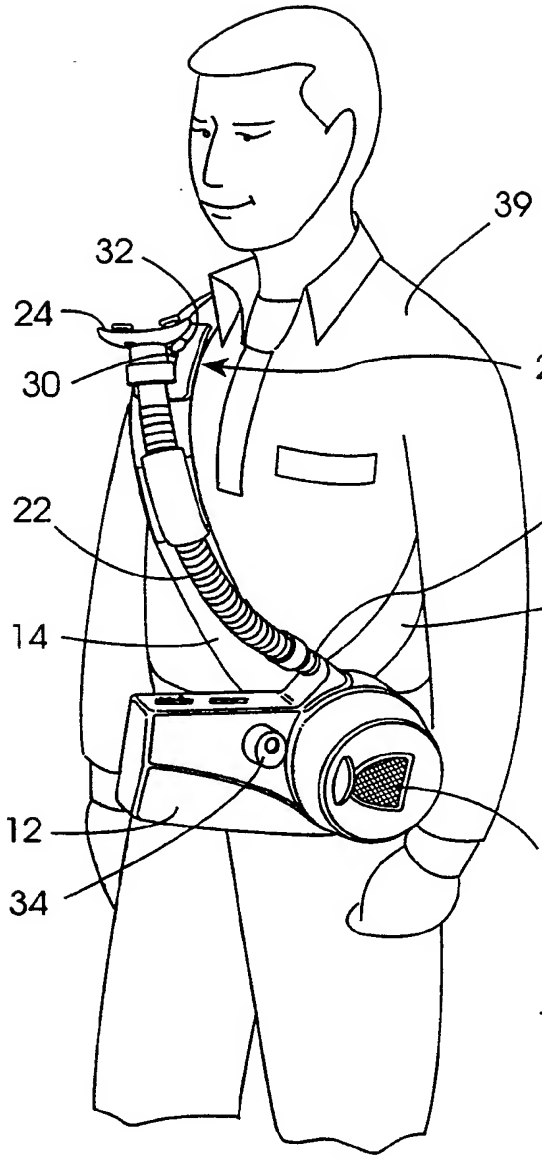

Fig. 2

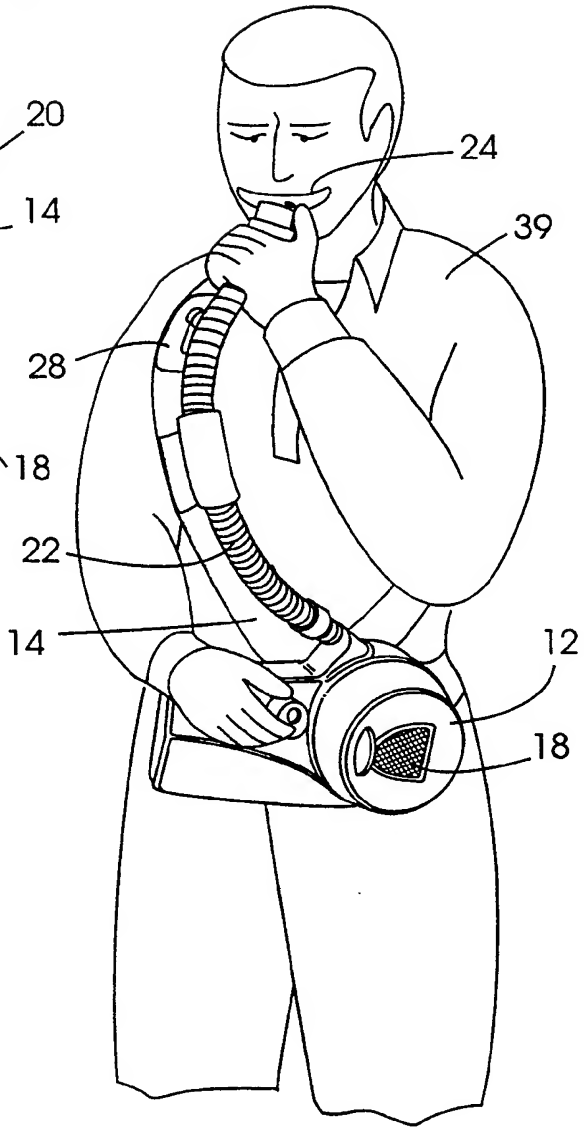

Fig. 3

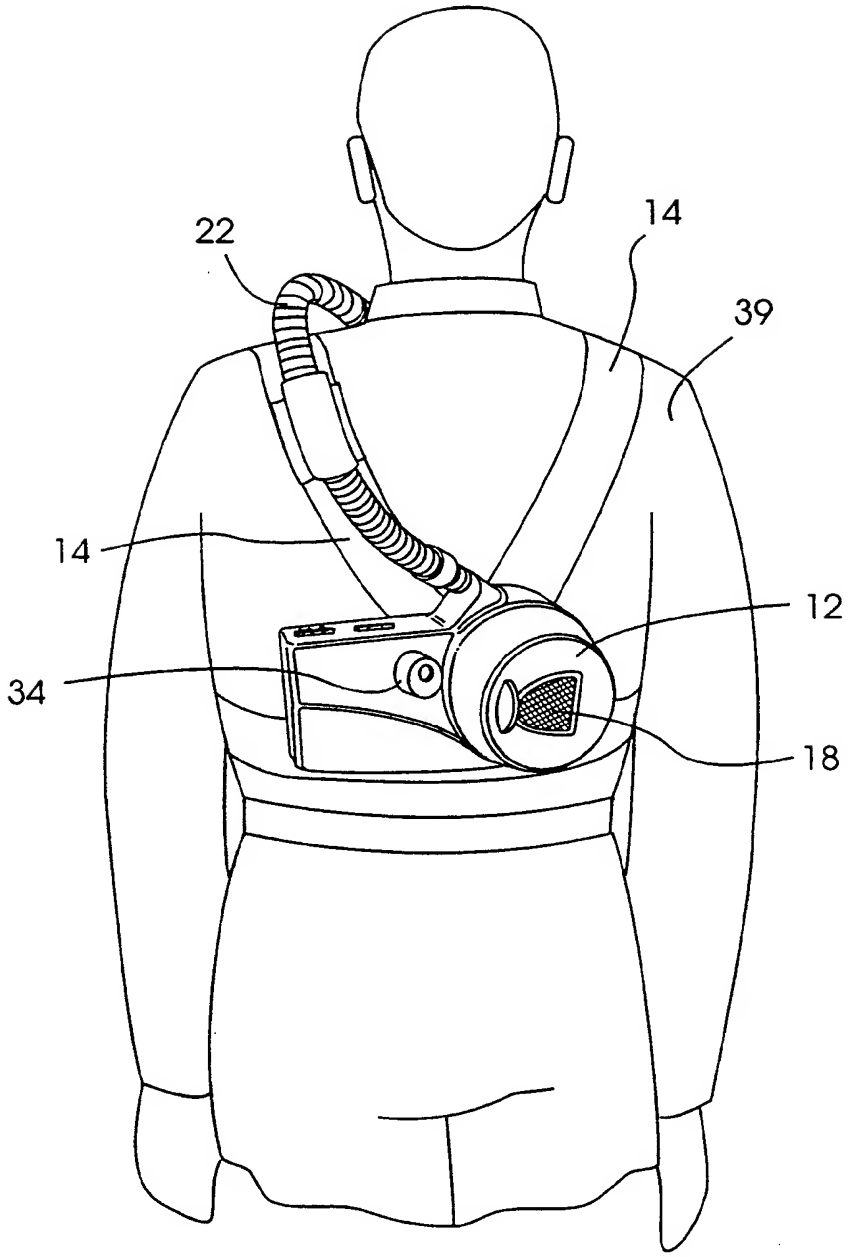

Fig. 4

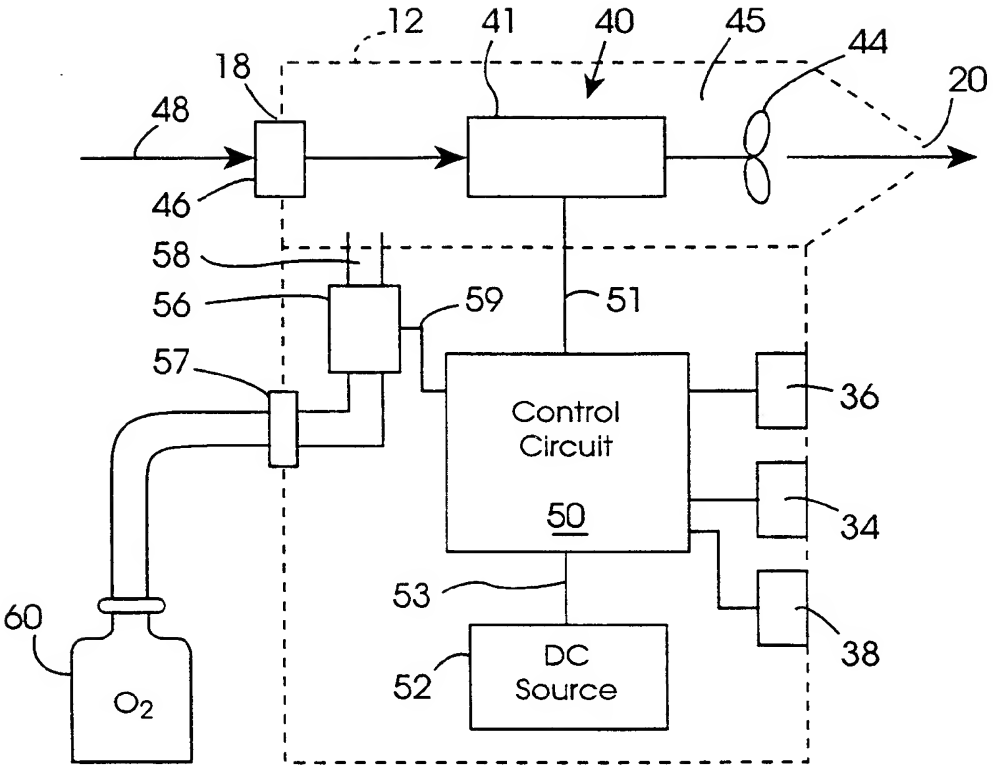
12
41
40
45
44
18
20
48
46
58
56
59
51
57
Control
Circuit
50
36
34
38
53
52
DC
Source
60
O_2

Fig. 5

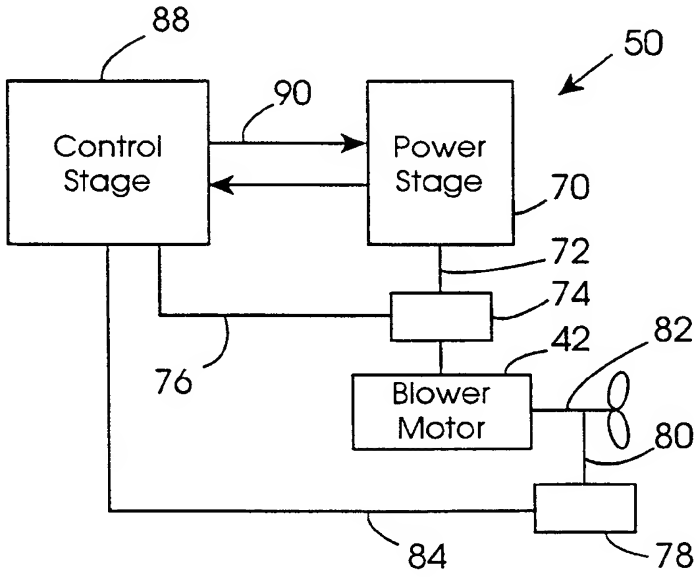
88
50
90
Control
Stage
Power
Stage
70
72
74
76
42
82
Blower
Motor
80
84
78

Fig. 6

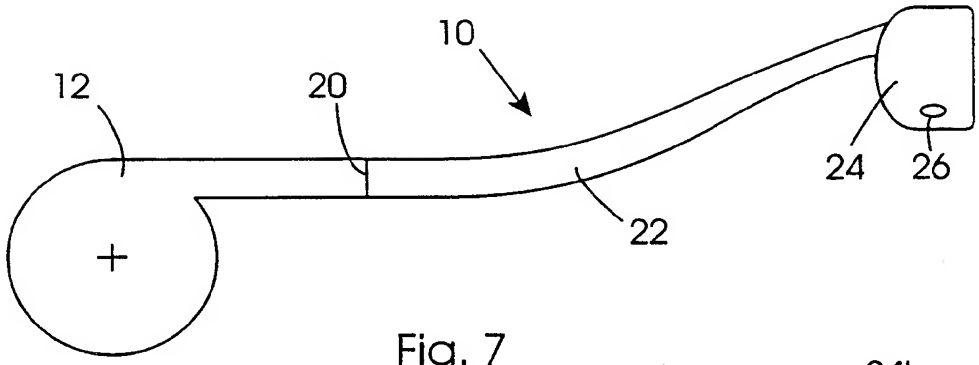
10
12
20
24
26
22

Fig. 7

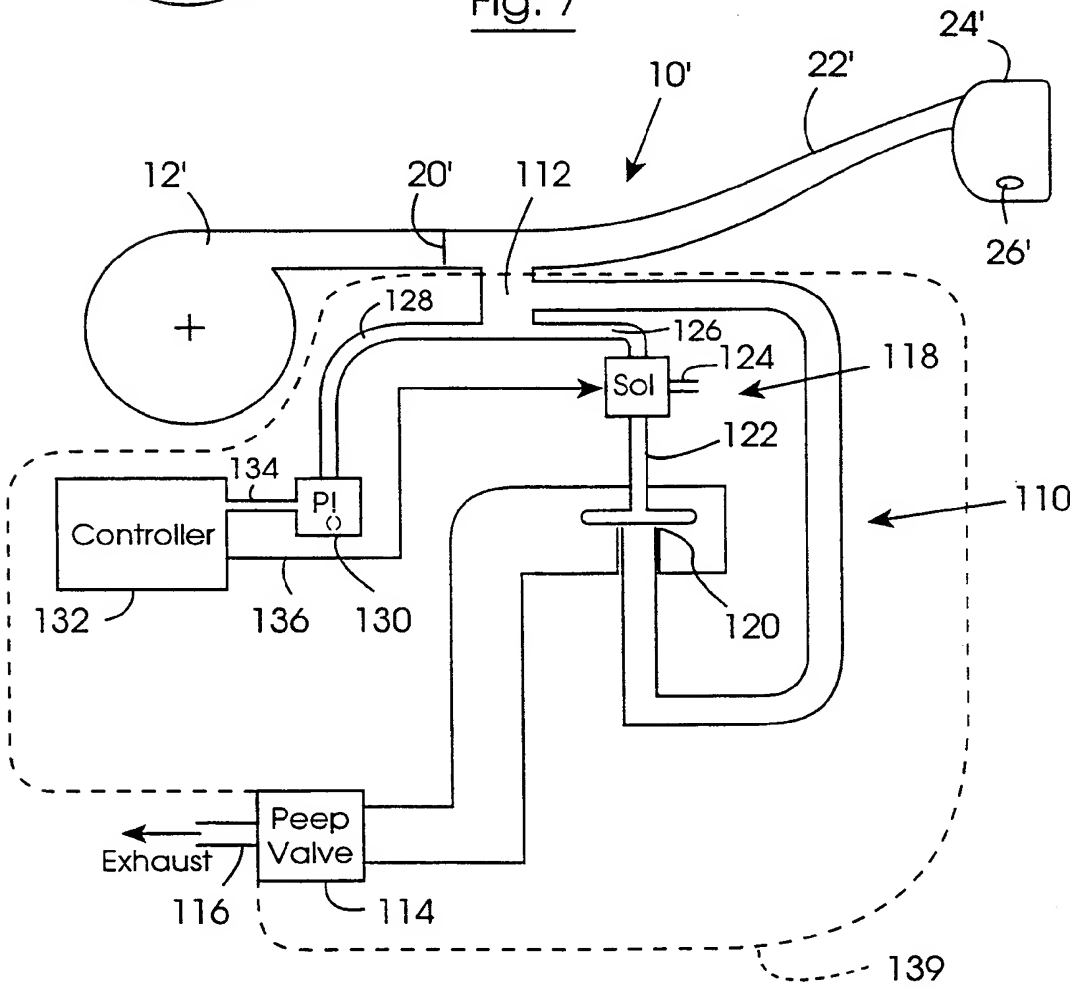
24'
10'
22'
12'
20'
112
26'
128
126
124
118
Sol
122
134
PI
110
Controller
132
136
130
120
Peep
Valve
Exhaust
116
114
139

Fig. 8

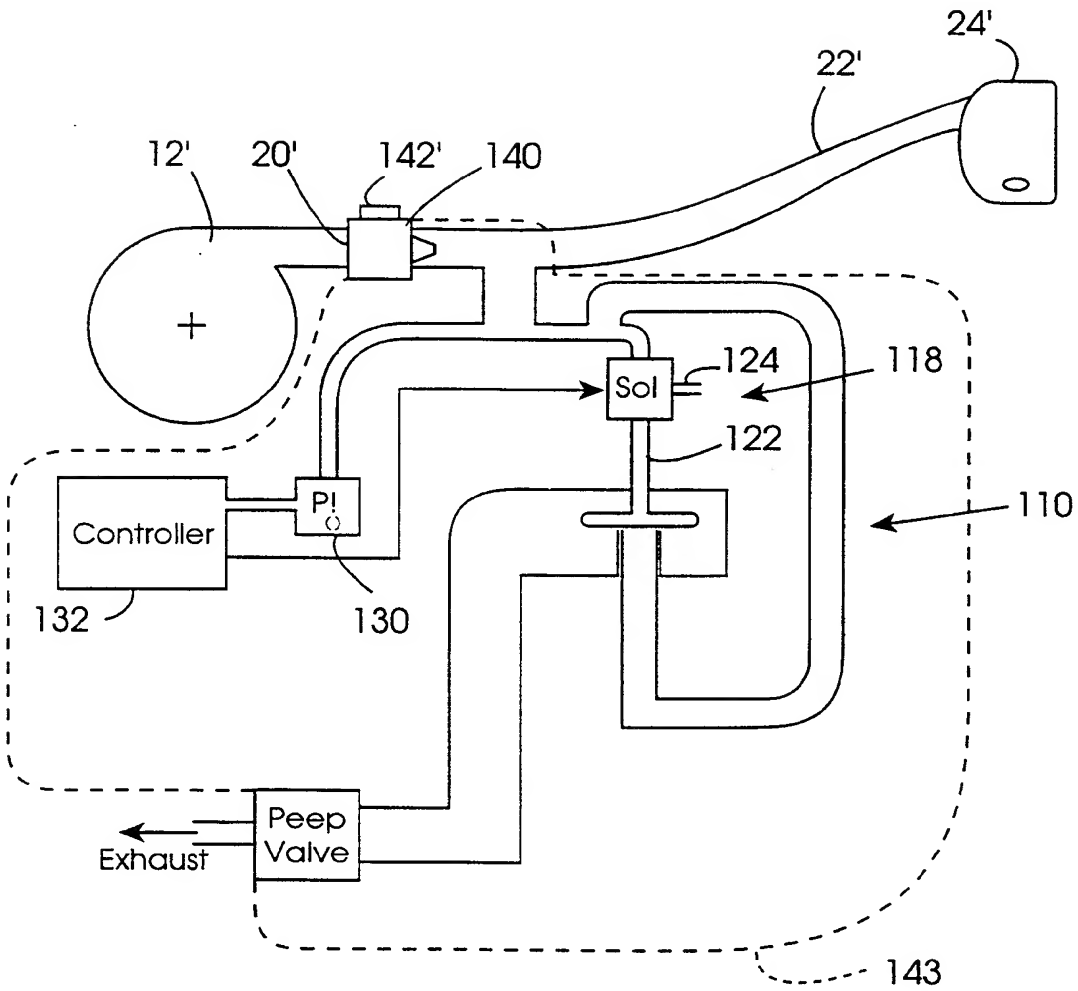
24'
22'
12'
20'
142'
140
124
118
Sol
122
110
Controller
PI
132
130
Peep
Valve
Exhaust
143

Fig. 9

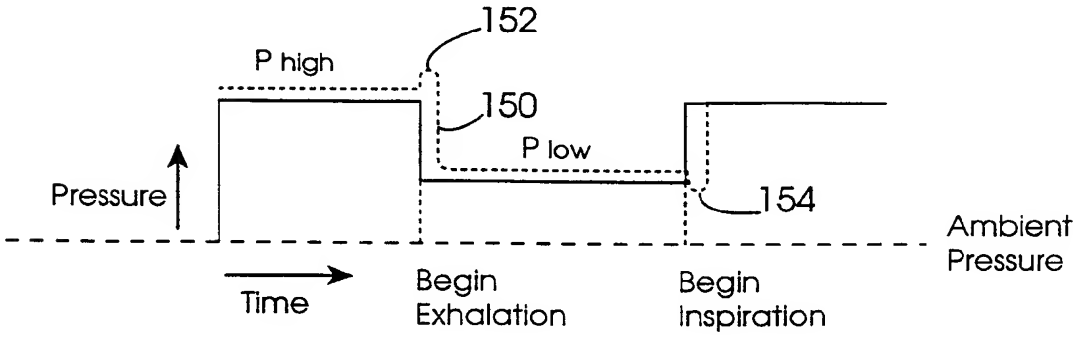
152
P high
150
P low
154
Pressure
Ambient
Pressure
Time
Begin
Exhalation
Begin
Inspiration

Fig. 10

INTERNATIONAL SEARCH REPORT

Inte· ·ional Application No
PCT/IE 98/00079

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M16/00 A61M16/20 A61M16/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A62B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 4 079 735 A (GAFFNEY JOHN P) 21 March 1978 see abstract; figures see column 2, line 16 - line 64 ---	11,16 12-15, 17-19
Y	EP 0 549 299 A (RESCARE LTD) 30 June 1993 see abstract; figures see page 3, line 29 - page 4, line 30 ---	12,13
Y	US 4 905 688 A (VICENZI RENO L ET AL) 6 March 1990 see abstract; figure 1 see column 3, line 12 - line 22 see column 5, line 52 - column 6, line 21 see column 7, line 49 - line 53 --- -/--	14,17

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 December 1998	22 02 1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	ZEINSTRA, H

2

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 98/00079

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 190 080 A (VIROX PTY LTD) 6 August 1986 see abstract; figures 1-3 see page 5, line 22 - line 35 see page 8, line 11 - line 20	15
Y	WO 89 02761 A (SPOFFORD BRYAN T ;CHRISTOPHER KENT L (US)) 6 April 1989 see abstract; figure 21 see page 26, line 1 - line 20	18
Y	WO 95 32016 A (UNIV NEW YORK ;PURITAN BENNETT CORP (US)) 30 November 1995 see abstract; figures 18,19 see page 25, line 7 - page 26, line 1	19

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

rnational application No.
PCT/IE 98/00079

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-10
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

11-19

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 11-19

   Shoulder strap for a portable respirator, comprising a releasable coupling.

2. Claim: 20

   System for introducing supplemental oxygen in the air channel.

3. Claims: 21-30, 31-36, 37-38, 39, 40, 41

   Diversion system for respirator, with pressure sensor.

INTERNATIONAL SEARCH REPORT

...formation on patent family members

Inter ...ional Application No
PCT/IE 98/00079

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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